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## **REMARKS**

This is a response to the Final Office Action dated October 7, 2003. Reconsideration of the claims based on the remarks provided below is respectfully requested. Claims 105 to 125 have been canceled without prejudice so that claims 1 to 104 and 126 to 148 are pending.

First, applicant appreciates Examiner Morgan and Supervisory Examiner Thomas' time and consideration during a telephonic interview on December 21, 2003 with Applicant's attorney. The restriction requirement and 35 U.S.C. 103 rejections were discussed. Applicant's attorney agreed to set forth the arguments presented at the interview in an amendment and amend the independent claims. Examiners Morgan and Thomas agreed to reconsider the restriction requirement and the 103 rejections and provide an advisory action.

Regarding the restriction requirement, the Examiner asserted that the newly submitted claims recited "on-line consent to <u>volunteering for consideration</u> as a potential candidate for one of a potential clinical trial and a clinical trial in progress" (emphasis in original; Office Action, page 2, paragraph 2) and that such recitation is independent of or distinct from the invention as originally claimed. The Examiner then provided that under 37 CFR. 1.142(b) and MPEP 821.03, since an action on the merits for the originally filed claims was already received, the invention was constructively elected. As a result, the Examiner argued that the restriction requirement was properly asserted in a Final Office Action.

However, as applicant's attorney presented at the interview, the newly added claims and, in particular, the volunteering for consideration for clinical trials element of such claims, was set forth in originally filed claims 1, 25, 31 as well as claims 56, 59. 60 and 61 provided in the preliminary amendment. More particularly, claim 1 as originally filed is as follows:

1. A method for using a system for on-line recruitment of candidates for clinical trials comprising the step of:

receiving over a network from a computer terminal an end user's on-line consent to an electronic agreement relating to volunteering as a potential candidate for a clinical trial and the release of at least one of medical and personal information.



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Newly added claim 73 recites:

73. A method for using a system for on-line recruitment of candidates for clinical trials comprising the step of:

receiving over a network from a computer terminal an individual's on-line consent to an electronic agreement for volunteering for consideration as a potential candidate for one of a potential clinical trial and a clinical trial in progress.

Claim 1 includes "volunteering as a potential candidate." This is equivalent to "volunteering for consideration as a potential candidate." The added phrase in claim 73, "for consideration," merely sets forth explicitly what is implicit. Namely, since the individual is only a potential candidate, some consideration is necessary in order to determine whether the potential candidate should be selected. Claim 1 recites "for a clinical trial." The added phrase in claim 73, "for one of a potential clinical trial and a clinical trial in progress," merely specifies different options for clinical trials and is more narrow than the general clinical trial. Neither of these phrases renders claim 73 independent of or distinct from claim 1. As a result, claim 73 is an example of a newly added claim which is not independent of nor distinct from the invention as previously claimed. Therefore, 37 CFR. 1.142(b0 and MPEP 821.03 were improperly applied to make final an Office Action. Applicant accordingly respectfully requests that the finality of this Office Action be withdrawn.

Furthermore, applicant respectfully submit that the claims as amended are not subject to a restriction requirement. The claims as amended herein are generally directed to a system or method of on-line recruitment involving an individual's agreement to release personal or medical information and/or the creation of a database of volunteers available for recruitment. In addition, several independent and dependent claims are directed to a specific type of recruitment, namely, for clinical trials. As a result, the claims as amended herein as not independent of or distinct from each other. Moreover, even if an argument could be made that particular claims are independent of or distinct from other claims, the search and examination for this prosecution involve a recruiting system and method and a resulting database. Applicants submit that a search and examiner of the entire application can be made without serious burden so that applicants respectfully request that the Examiner consider the entire set of claims on the merits without any further restriction requirement.

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Therefore, applicants respectfully submit that the finality of this Office Action is improper. As a result, applicants provide substantive amendments to the pending claims and request that the amendments be entered and considered in response to this communication. More particularly, independent claims 1, 25, 31, 73, 131, 132, 134, 138, 141, 143 and 147 have been amended to more clearly recite the invention. Multiple dependent claims have also been amended. Support for the claim amendments is as follows:

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- (a) Claims 1, 25, 31, 73, 131, 132, 134, 138, 141 and 143, the "volunteer database" element: the specification as originally filed, claim 20 recited a list of volunteers, claim 31 recited the release of medical data, claim 34 recited data entered, claims 38 and 45 recited data stored in a memory, claim 46 recited retrieving data, on page 6, lines 12 to 14 is described entering data, on page 7, lines 16 to 17 is described storing the data in a memory device and on page 8, lines 23 to 24 is described a database of volunteers.
- (b) Claims 15, 46, 89, the "authorized individual" element, the specification as originally filed, on page 8, line 23 to page 9, line 9 is described the process of becoming an authorized officer of a clinical study.
- (c) Claims 20, 50, 57, 62, 96, 102, the "opt-out" process, the specification as originally filed, claim 20 etc., on page 8, lines 10 to 23 is described the opt-out procedure.
  - (d) Claim 53, 141, the specification as originally filed, claim 1.
  - (e) Claim 55, the specification as originally filed, claim 53.
- (f) Claim 56, 103, 104, 134, the "clinical trials" examples, the specification as originally filed claim, on page 4, lines 16 to 18 is described different types of clinical trials, on page 6, lines 24 to 26 is described how various clinical trial administrators can alter the data requested in the recruiting process, on page 8, lines 23 to 25 is described how various researchers or administrators of clinical trials can access the database, on page 10, lines 3 to 5 is described multiple clinical studies which have access to the volunteer database, Figure 3f, question 12.



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(g) Claim 73, 131, 132, receiving medical or personal information, the originally filed specification, Figure 3a to 3f.

The Examiner maintained his rejection of the pending claims under 35 USC 103 based on U.S. Patent No. 5,991,731 to Colon et al, U.S. Patent No. 6,171,112 to Clark et al and Official Notice. Applicants respectfully submit that the combination of Colon, Clark and Official Notice did not teach each element of any of the independent claims pending as of the Office Action. However, each independent claim has been further amended and such amendments more clearly demonstrate the differences between the invention as claimed and the prior art. More particularly, each of claims 1, 25, 31, 73, 131, 132, 134, 138, 141 and 143 recites adding either medical or personally identifying information about the individual to a database of recruits/volunteer or a database including such information. This element is not taught by either Clark or Colon. Claim 147 is directed to analyzing information in a database. This elements also is not taught by Clark or Colon.

Since at least one element of each of the independent claims (and likewise the claims which depend from them) are not taught by the cited prior art, applicant respectfully submits that each of the presently pending claims is believed to be in immediate condition for allowance.

Accordingly, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

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